**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF ILLINOIS**

**UNITED STATES OF AMERICA *et al.***
***ex rel.* ELISA DICKSON, Relator,**

**Plaintiffs,**

**v.**

**BRISTOL MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., LLC; SANOFI-AVENTIS U.S., INC.; and SANOFI-SYNTHELABO, INC.,**[1]

**Defendants.** **No. 11-cv-246-DRH-SCW**

**MEMORANDUM & ORDER**

**HERNDON, Chief Judge:**

## I. INTRODUCTION

Pending before the Court is defendants' collective motion to dismiss relator's second amended complaint (Doc. 43). Relator has filed her response in opposition (Doc. 52). For the following reasons, defendants' motion is **DENIED in part and GRANTED in part** (Doc. 43).

## II. BACKGROUND

For a detailed discussion of the background of this dispute and the parties' respective arguments, the Court refers the reader to the briefs on file. In sum, defendants' instant motion argues relator's second amended complaint should be

[1] Defendants state they were incorrectly designated in the complaint. **The Clerk is instructed to change defendants' respective designations to reflect the following: Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc.**

dismissed with prejudice pursuant to FEDERAL RULES OF CIVIL PROCEDURE 12(b)(1), 12(b)(6), and 9(b), as it presents inadequately pled and legally defective claims that fail to state a proper claim under the federal False Claims Act (FCA) or any analogous state statute. While defendants' instant arguments may gain more traction at the summary judgment level, at present, the second amended complaint (Doc. 38) sufficiently alleges actionable claims.[2]

## III. LAW AND APPLICATION

### 1. Sufficiency of False Claims Act Allegations

First, defendants argue relator's allegations fail to state a claim under the FCA and thus require dismissal under Rule 12(b)(6). As to the standard the Court shall apply to test the sufficiency of relator's allegations, Rule 12(b)(6) dismissal is warranted if the complaint fails to set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The Seventh Circuit has stressed: "surviving a Rule 12(b)(6) motion requires more than labels and conclusions;" the allegations must "raise a right to relief above the speculative level." *Pugh v. Tribune Co.*, 521 F.3d 686, 699 (7th Cir. 2008). Similarly, the court remarked in *Swanson v. Citibank, N.A.*, 614 F.3d 400, 403 (7th Cir. 2010): "It is by now well established that a plaintiff must do better than putting a few words on paper that, in the hands of an imaginative reader, might suggest that something has happened to her that might be redressed by the law." *See Ashcroft v. Iqbal,* 556 U.S. 662 (2009).

[2] This statement holds true except as to relator's fourth cause of action, as explained fully at the end of this Order.

In making this assessment, the district court accepts as true all well-pled factual allegations and draws all reasonable inferences in relator's favor. *See Rujawitz v. Martin*, 561 F.3d 685, 688 (7th Cir. 2009); *St. John's United Church of Christ v. City of Chicago*, 502 F.3d 616, 625 (7th Cir. 2007).

To plead a claim under 31 U.S.C. § 3729(a)(1), relator must allege: "(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740-41 (7th Cir. 2007) (internal quotation marks and citation omitted), *overruled in part on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). Similarly, to plead a claim under 31 U.S.C. § 3729(a)(2),[3] relator must allege: "(1) the defendant made a statement in order to receive money from the government, (2) the statement was false, and (3) the defendant knew it was false." *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005).

Relator alleges defendants, "have acted in a comprehensive scheme to defraud federal and state governments while illegally and deceptively promoting Plavix to further increase Plavix sales" (Doc. 38, p. 18, para. 46). Specifically, relator alleges: "defendants manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy compared to cheaper alternatives;" "fraudulently

[3] In 2009, Congress amended Section 3729(a)(2) and re-designated it as Section 3729(a)(1)(B). *See* History to 31 U.S.C. § 3729. Sister courts in this circuit have continued to apply this same § 3729(a)(2) three-element standard for § 3729(a)(1)(B) claims. *See United States ex rel. Walner v. Northshore Univ. Healthsystem*, 660 F. Supp. 2d 891, 896 n. 4 (N.D. Ill. 2009) (Kendall, J.). While obviously not binding on this Court, this reasoning seems persuasive at this time.

downplayed and misrepresented specific and known health risks of Plavix use compared to cheaper alternatives;" "mischaracterized clinical studies which contradicted the sales campaign;" and "targeted doctors whose patients rely on government payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers" (Doc. 38, pp. 19-26). Thus, relator alleges that defendants knowingly provided false information regarding the efficacy of Plavix compared to cheaper alternatives, which caused physicians and pharmacists to either expressly or impliedly make false certifications about Plavix's efficacy or necessity for the patient's treatment. Consequently, defendants knowingly caused the submission of false claims for payment by government payors.

Relator's allegations are sufficient under *Twombly* and *Iqbal*. As a prerequisite to Medicare payment, the particular item or service must be "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A); *see also Mikes v. Straus*, 274 F.3d 687, 700-701 (2d Cir. 2001) (stating, "[s]ince § 1395y(a)(1)(A) *expressly* prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision); *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (noting, the Medicare Act "precludes reimbursement for services which are not 'reasonable and necessary' for the diagnosis or treatment of illness or injury").

Accepting relator's allegations as true, relator alleges defendants' fraudulent actions caused physicians and pharmacists to submit claims for reimbursement

of prescribed treatment that was not "reasonable and necessary" and thus false. While defendants seem to argue relator's theory of recovery is foreclosed in the Seventh Circuit, defendants have not produced authority binding on this Court that conclusively demonstrates as such, nor has the Court's independent search revealed the same. Thus, on the basis of the record currently before the Court, the Court will not hold relator's claims are insufficient to state a claim that is plausible at this stage in the proceedings.

Further, defendants argue relator fails to allege a "false or fraudulent" claim because relator's allegations relate entirely to prescriptions of Plavix for its FDA-approved indications. However, as relator points out, the fact a drug is FDA-approved, does not mean it is "reasonable and necessary" in every instance it is prescribed. *Almy v. Sebelius,* 679 F.3d 297, 308 (4th Cir. 2012) (generally stating that in the Medicare context, while FDA approval may inform the decision as to whether a device is "reasonable and necessary," "it cannot tie the Secretary's hands"). Relator alleges defendants instructed their sales force to present various data and studies in a manner designed to confuse physicians and make them believe that Plavix was more effective than cheaper alternatives. Thus, defendants' misrepresentations caused physicians to feel that Plavix was essentially their only option.

Further, relator alleges defendants specifically instructed their sales force (relator included) to "focus sales calls on physicians who wrote significant numbers of prescriptions for patients covered by certain government payors"

(Doc. 38, para. 22). Although there can be instances where Plavix was properly prescribed, this does not preclude relator's ability to state a plausible FCA claim. Drawing all inferences in relator's favor, it appears an allegation that defendants caused physicians to certify that Plavix was reasonable and necessary when it was not, sufficiently states a plausible claim under the FCA at this stage in the proceedings. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011) (noting that FCA makes no distinction between how non-submitting and submitting entities may render the underlying claim or statement false or fraudulent).

**2. Public Disclosure Bar**

Defendants next argue relator's FCA claims are prohibited by the public disclosure bar to the FCA and thus require dismissal under Rule 12(b)(1) and 31 U.S.C. § 3730(e)(4)(A) for lack of subject matter jurisdiction. In a nut-shell, defendants argue relator has not met her burden of establishing subject matter jurisdiction because she cannot meet the requirements of Section 3730(e)(4)(A). Relator disagrees with defendants' substantive assertions and alternatively argues this dispute is best resolved later in the proceedings.

Generally, the FCA authorizes an individual acting as a relator to bring a civil action on behalf of the United States to remedy a fraudulent claim for payment, but bars actions if based upon or substantially similar to public disclosures, unless the person bringing the action is an "original source of the

information." *See* 31 U.S.C. § 3730(e)(4)(A).[4] Defendants have chosen Rule 12(b)(1) as the vehicle through which to present their instant arguments and ask the Court to consider numerous documents outside of the pleadings. While the Court acknowledges that this choice may be procedurally proper, *see Glaser*, 570 F.3d at 912-913,[5] the Court finds the record in this case is not adequate to make such a factual determination at this stage in the proceedings and declines to do so. Defendants will be able to renew their arguments when the record is better developed.

**3. Sufficiency Under Rule 9(b)**

Finally, defendants argue relator's claims require dismissal as they do not meet the standards of Rule 9(b). Rule 9(b) provides a higher standard of pleading than the typical "notice" standard under Rule 8. Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

As the FCA is an anti-fraud statute, claims under it are subject to the heightened pleading requirements of Rule 9(b). *See Gross*, 415 F.3d at 604;

[4] The Court notes 31 U.S.C. § 3730(e)(4)(A) was amended in 2010 as a part of the Patient Protection and Affordable Care Act of 2010 (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010). While the parties seem to agree that the post-2010 version applies to false claims submitted on or after March 23, 2010, the parties seem to dispute whether the pre-2010 or post-2010 version of the statutes applies to false claims submitted before that date. However, the Court has not been asked to resolve this dispute at this time and thus it declines to comment at to which version applies to the entirety of the alleged false claims at issue.

[5] However, the Court would like to note that *Glaser* was decided before the recent PPACA amendments. While this may have no impact on the dispute at hand, it is merely noted that certain "jurisdictional" language is no longer present in the current version of the statute. *See* post-2010 version of 31 U.S.C. § 3730(e)(4)(A) ("The Court *shall dismiss* an action or claim under this section . . . ) (emphasis added); *compare with* pre-2010 version of 31 U.S.C. § 3730(e)(4)(A) ("[n]o court *shall have jurisdiction* over an action under this section . . . ) (emphasis added).

*United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374 (7th Cir. 2003). However, Rule 9(b) does not require a plaintiff to plead evidence and is to be read in conjunction with Rule 8, which requires a short and plain statement of the claim, s*ee Tomera v. Galt*, 511 F.2d 504, 508 (7th Cir. 1975), and in light of its purposes, which include: "(1) protecting a defendant's reputation from harm; (2) minimizing 'strike suits' and 'fishing expeditions;' and (3) providing notice of the claim to the adverse party." *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994). Further, sister courts in this circuit have recognized that when a relator alleges fraud under the FCA over an extended period of time, the requirements of Rule 9(b) may be tempered somewhat, as a relator alleging fraud, prior to discovery, may not have access to all the facts necessary to provide details. *See United States v. Pekin Mem'l Hosp.*, 2008 WL 2705443, *4 (C.D. Ill. July 9, 2008) (McDade, J.); *United States ex rel. Trombetta v. EMSCO Billing Servs., Inc.*, 2002 WL 34543515, *4 (N.D. Ill. Dec. 5, 2002) (Gottschall, J.).

Relator's instant allegations are sufficient to comport with the requirements of Rule 9(b) in this instance. Relator alleges defendants instructed relator and other members of the sales force to promote Plavix as having certain characteristics that defendants knew it did not possess which caused physicians to submit false claims to the government. Relator alleges that despite the non-significant efficacy data in certain trials for stroke patients, she personally was instructed to promote Plavix as being superior to aspirin in stroke patients.

Defendants are the alleged source of the misrepresentations. As to which specific physicians such misrepresentations were allegedly made, and further which specific employees of defendants' instructed relator to make such misrepresentations, such details can be fleshed out in discovery.[6]

Relator states with adequate particularity the circumstances of defendant's fraudulent scheme. Relator relates, in detail, allegations of defendants' manipulation of certain clinical trial data, misrepresentation of specific and known health risks of Plavix, mischaracterization of specified clinical studies which allegedly contradicted defendants' sales campaign, and targeting of doctors whose patients rely on government payors for health care treatment to inflate sales at a tremendous cost to taxpayers. Relator alleges these misrepresentations were presented to physicians through their sales representatives, causing physicians to submit false claims to the government.

Finally, relator provides specific dates and locations related to the alleged misrepresentations. For example, relator states that on May 9, 2001, the FDA's Division of Drug Marketing and Communications sent defendant Sanofi a letter objecting to its promotional efforts for Plavix. More generally, relator's complaint refers repeatedly to the CAPRIE study, published in 1996, and states defendants thereafter used said study to falsely promote Plavix.

---

[6] With significant reliance on *Fowler*, 496 F.3d at 741-742, *Garst*, 328 F.3d at 376, and various district court opinions which are not binding on this Court, defendants argue that relator is required at this stage in the proceedings to identify specific claims actually submitted which relator alleges were false. The Court does not feel such specificity is required in this instance. *See generally United States ex rel. Wildhirt v. AARS Forever, Inc.*, 2011 WL 5373985, *1 (N.D. Ill. Nov. 4, 2011) (citing *Fowler* and noting that an allegation that defendant made a "statement" in connection with a specific presentation to the government for payment is only one way of pleading the first element of a *qui tam* action).

Specific to relator, relator states she has worked in the pharmaceutical industry for approximately twelve years and is currently a sales representative specializing in the sale of Plavix. She began working for defendant Bristol-Myers Squibb Company in 1999 and took a sales representative position at defendant Sanofi in 2003. She further states from 2008 to 2010, her primary sales efforts were concentrated on selling Plavix to primary care physicians. Relator alleges she received training as to defendants' allegedly fraudulent promotional tactics in St. Louis, Missouri in September 2003 and in Dallas, Texas in 2008. Thus, accepting these allegations as true, relator's claims sufficiently provide the particularity required under Rule 9(b) in this instance. However, the Court reminds the parties that, "[t]o say that fraud has been *pleaded* with particularity is not to say that it has been *proved*," and therefore relator's allegations could very well be wrong. *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009). At this point, however, the Court merely finds the allegations of the amended complaint survive the requirements of Rule 12(b)(6) and 9(b).[7]

**4. State Law Claims**

Lastly, defendants argue relator's claims based on the false claims and Medicaid claims statutes of 26 different states or localities that are substantively similar to and/or track the language of the FCA must likewise be dismissed for all of defendants' above-stated reasons and for "fail[ure] to comply with the qui tam

[7] The Court notes the parties argue back and forth within their respective footnotes as to the adequacy of relator's conspiracy allegations. The Court finds defendant has not sufficiently raised any argument pertaining to relator's conspiracy allegations to warrant review at this time.

provisions of the state false claims acts" (Doc. 44, p. 32) (citing *United States ex rel. Fowler v. Caremark RX, Inc.*, 2006 WL 1519567, * 5 (N.D. Ill. May 30, 2006) (Conlon, J.)). To the extent defendants' arguments mirror those above, they are denied for the reasons stated above. Further, to the extent defendants generically argue relator has failed to comply with the various state *qui tam* provisions, such argument is too vague to meaningfully address at this time.

Finally, in footnotes, defendants specifically address two of relator's separate state law/municipal code claims. First, Defendants separately seek dismissal of relator's claim under the Illinois Public Assistance Fraud Act. *See* 305 Ill. Comp. Stat. Ann. 5/8A-1, *et seq.*, as it does not provide for a private cause of action. Relator, also in a footnote, agrees with defendants and requests voluntary dismissal of her fourth cause of action. The Court grants relator's requests and thus **dismisses relator's fourth cause of action without prejudice**.

Second, in relator's twenty-first cause of action, relator brings a claim for violation of the City of Chicago False Claims Act. *See* Chicago Mun. Code § 1-22-010- § 1-22-060. That ordinance empowers private parties to "bring a civil action *against a city contractor* for [submitting a false claim] . . . in the name of the city." *See* Chicago Mun. Code § 1-22-030, *available at http://www.amlegal.com/nxt/gateway.dll/Illinois/chicago_il/title1generalprovisions/chapter1-22falseclaims?f=templates$fn=altmain-nf.htm$3.0#JD_1-22-020* (emphasis added). Thus, defendants argue relator's claim under this ordinance should be dismissed because relator does not allege that defendants are city contractors. In response, relator states she does not have to use the phrase "city

contractor," as she alleges defendants caused the Chicago City Government to approve and pay false and fraudulent claims (impliedly received from healthcare providers).

The provision defines "city contractor" as, "a person who enters into a contract *or who has taken any action to obtain a contract,* or any owner, officer, director, employee or agent of such a person, or any subcontractor, or any person acting in concert or conspiring with such person." *See* Chicago Mun. Code § 1-22-010 (emphasis added). Thus, based on relator's theory of recovery and defendants' specific argument, it seems she has stated a plausible claim under this section at this time.[8]

## IV. CONCLUSION

For the above-stated reasons, defendants' motion to dismiss relator's second amended complaint (Doc. 43) is **DENIED in part and GRANTED in part**.

**IT IS SO ORDERED.**

Signed this 30th of January, 2013.

Digitally signed by David R. Herndon
Date: 2013.01.30 11:43:57 -06'00'

**Chief Judge**
**United States District Court**

[8] The Court notes defendants filed a response in opposition to relator's request for expedited ruling (Doc. 53). In part, defendants oppose expedited ruling as they would like the opportunity to seek leave to file a reply to relator's response in opposition (Doc. 52). However, the Court reminds defendants that "reply briefs are not favored and should only be filed in exceptional circumstances." *See* SDIL-LR 7.1(c)(2). While defendants' opposition to expedited ruling would have provided defendants the perfect opportunity to indicate what exceptional circumstances warrant a reply, they chose not to do so. Defendants also oppose an expedited ruling on the basis that it would be better to leave a ruling on the current motion to a transferee judge in the event the JPML consolidates this lone *qui tam* case with the other Plavix cases pending on the docket for such consideration. This judge knows quite well that transferee judges prefer for motions of this type to be cleared by transferor judges prior to consolidation. Likewise, the JPML encourages such prior rulings.